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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/12/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/526,193

Applicant(s)

HAYDEN ET AL.

Examiner

David J. Steadman

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 January 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 159 and 160.Claim(s) rejected: 135, 136, 142-145, 147-151, 156-158, 161-163, 165, 166, 168, 169, 172-176, 178-181, 187, 191 and 213-225.Claim(s) withdrawn from consideration: 184-186, 188-190 and 192-194.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: interview summary

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ADVISORY ACTION

1. Claims 135, 136, 142-145, 147-151, 156-163, 165, 166, 168, 169, 172-176, 178-181, 184-190, 192-194, and 213-225 are pending in the application.
2. Claims 184-186, 188-190, 192-194 remain withdrawn from consideration.
3. Claims 135, 136, 142-145, 147-151, 156-158, 161-163, 165, 166, 168, 169, 172-176, 178-181, 187, 191, and 213-225 stand finally rejected.
4. Claims 159 and 160 are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. The request for reconsideration in the after final amendment of Paper No. 23, filed 01/09/03, is acknowledged. The amendment would appear to overcome the objection and rejection under 35 USC 112, second paragraph as set forth in items 3-10 of Paper No. 21. However, the amendment does not place the claims in condition for allowance because the amendment would require a new search and further consideration of the claims. See MPEP 714.13 regarding non-entry of after final amendments.
6. Regarding a new search and further consideration of the claims, the limitation of a polypeptide comprising an amino acid sequence with at least 50 % identity to SEQ ID NO:1 has been newly added to the claims (see particularly claims 143 and 213). This limitation has not been presented in originally filed or previously amended claims and thus would require a new search and further consideration of the claims.
7. The drawings remain objected to by the draftsman. Applicants state that new drawings will be submitted. However, as of the drafting of this Office action, such drawings had not been entered into the instant application. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

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8. The objection to claim 181 is maintained. Applicants argue the objection has been overcome by claim amendment. However, in view of the non-entry of the amendment, the objection is maintained for the reasons of record. It is noted that the amendment would appear to overcome this objection.

9. The rejection of claims 135, 136, 142, 161-166, 168, 169, 172-176, 178, 184-186, and 188 under 35 U.S.C. 112, second paragraph, is maintained. Applicants argue the rejection has been overcome by claim amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome this rejection.

10. The written description rejection of claims 143-145, 148, 149, 151, 156-158, 176, 178-181, and 213-225 under 35 U.S.C. 112, first paragraph, is maintained. Applicants argue the rejection has been overcome by claim amendment. Applicants argue the specification adequately describes the genus of ABC1 polypeptides of claims 143 and 213 as this genus has been limited structurally by the recitation of having at least 50 % identity to the polypeptide of SEQ ID NO:1. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome this rejection.

11. The scope of enablement rejection of claims 143-145, 148, 149, 151, 156-158, 176, 178-181, and 213-225 under 35 U.S.C. 112, first paragraph, is maintained. Applicants argue the rejection has been overcome by claim amendment. Applicants argue the specification discloses a representative number of ABC1 polypeptides to enable the polypeptide as recited in claims 143 and 213 having at least 50 % identity to the polypeptide of SEQ ID NO:1. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would not appear to overcome this rejection. Undue experimentation would be required for a skilled artisan to make and use the entire scope of recited polypeptides used to practice the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

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predictability or unpredictability of the art, and (8) the breadth of the claim(s). The specification provides insufficient guidance for making the entire scope of recited ABC1 polypeptides. The specification discloses only a single working example of the recited polypeptides, i.e., SEQ ID NO:1. Neither the specification nor the prior art provides guidance for making or isolating all polypeptides with at least 50 % sequence identity to SEQ ID NO:1 and having lipid transport activity, as encompassed by the instant claims. Based on the specification and the prior art, it appears that ABC1 polypeptides having N-terminal amino acids 1-60 were not conventional in the art or known to one of skill in the art. The specification discloses that human and mouse ABC1 polypeptides having an additional 60 amino acids at the N-terminus were not known (see pages 40 and 41 of the instant specification) and that based on studies using an antibody specific for an antigen in this 60 amino acid region, it appears that this region is present and conserved among human, mouse, and chicken ABC1 polypeptides (see pages 50 and 51 of the instant specification). Furthermore, applicants suggest that the previously unreported N-terminal amino acids 1-60 may be important in the function of the ABC1 polypeptide (page 51 of the specification), particularly in the transport of cholesterol (page 38 of the specification), which was not an assigned function of a human ABC1 polypeptide at the time of the invention (see page 19, top, of Paper No. 19). However, neither the specification nor the prior art provides any clear indication other than a suggestion to indicate that this region is important in lipid transport. Neither the specification nor the prior art provides guidance as to which amino acids are necessary for ABC1 lipid transport. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any

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protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

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